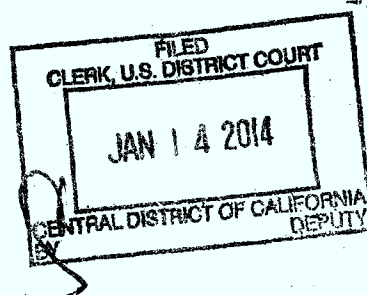


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16 UNITED STATES DISTRICT COURT
17 CENTRAL DISTRICT OF CALIFORNIA

18 UNITED STATES OF AMERICA
19 [UNDER SEAL],

20 Plaintiffs,

21 vs.

22 [UNDER SEAL],

23 Defendants.

CASE NO.: CV12-8797 MMM(PLA_x)

SECOND AMENDED COMPLAINT
FOR VIOLATIONS OF FEDERAL
FALSE CLAIMS ACT [UNDER
SEAL]

[UNDER SEAL PER 31 U.S.C. §
3730(b)(2)]

24 [UNDER SEAL]

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17 UNITED STATES DISTRICT COURT
18 CENTRAL DISTRICT OF CALIFORNIA

19 UNITED STATES OF AMERICA and THE
20 STATES OF CALIFORNIA, NEW YORK,
21 NEW JERSEY, FLORIDA, TEXAS,
22 MICHIGAN, MASSACHUSETTS,
23 MARYLAND and ILLINOIS, *ex rel*
24 STUART FINKELSTEIN, M.D.,

25 Plaintiffs,

26 vs.

27 RECKITT BENCKISER
28 PHARMACEUTICALS, INC., a Delaware
corporation, RECKITT BENCKISER
(USA), INC., a Delaware corporation, and
MONOSOL RX, LLC, a Delaware
corporation,

Defendants.

CASE NO.: CV12-8797 MMM(PLAx)

SECOND AMENDED COMPLAINT
FOR VIOLATIONS OF THE
FEDERAL FALSE CLAIMS ACT,
CALIFORNIA FALSE CLAIMS
ACT, NEW YORK FALSE CLAIMS
ACT, NEW JERSEY FALSE
CLAIMS ACT, FLORIDA FALSE
CLAIMS ACT, TEXAS FALSE
CLAIMS ACT, MICHIGAN FALSE
CLAIMS ACT, MASSACHUSETTS
FALSE CLAIMS ACT, MARYLAND
FALSE CLAIMS ACT, ILLINOIS
FALSE CLAIMS ACT; REQUEST
FOR JURY TRIAL

[UNDER SEAL PER 31 U.S.C. §
3730(b)(2)]

29 COMES NOW, Plaintiff and Qui Tam Relator Stuart Finkelstein, M.D., individually
30 and on behalf of the United States of America and the States of California, New York, New
31 Jersey, Florida, Texas, Michigan, Massachusetts, Maryland and Illinois, and alleges as follows:

32 ///

JURISDICTION AND VENUE

1
2 1. Plaintiff and Qui Tam Relator Stuart Finkelstein, M.D. (Relator) files this action
3 on behalf and in the name of the United States Government ("Government") seeking damages
4 and civil penalties against the defendants for violations of 31 U.S.C. § 3729(a). Relator also
5 files this action on behalf and in the name of the States of California, New York, New Jersey,
6 Florida, Texas, Michigan, Massachusetts, Maryland and Illinois (collectively, "Certain States")
7 seeking damages and civil penalties against the defendants for violations of California
8 Government Code § 12651(a), New York State Finance Law § 189(1), New Jersey Statutes
9 Annotated § 2A:32C-3, Florida Statutes § 68.082(2), Texas Human Resources Code § 36.002,
10 Michigan Comp. Laws §§ 400.603 and 400.607, Massachusetts General Laws Chapter 12, §§
11 5B, Maryland Code, Health General § 2-602(a), and 740 Illinois Comp. Stat. § 175/3,
12 respectively.

13 2. This Court's jurisdiction over the claims for violations of 31 U.S.C. § 3729(a)
14 is based upon 31 U.S.C. § 3732(a). This Court's jurisdiction over the claims for violations of
15 California Government Code § 12651(a), New York State Finance Law § 189(1), New Jersey
16 Statutes Annotated § 2A:32C-3, Florida Statutes § 68.082(2), Texas Human Resources Code
17 § 36.002, Michigan Comp. Laws §§ 400.603 and 400.607, Massachusetts General Laws
18 Chapter 12, §§ 5B, Maryland Code, Health General § 2-602(a), and 740 Illinois Comp. Stat.
19 § 175/3 is based upon 31 U.S.C. § 3732(b).

20 3. Venue is vested in this Court under 31 U.S.C. § 3732(a) because at least one of
21 the defendants transacts business in the Central District of California and many acts
22 constituting violations of 31 U.S.C. § 3729(a) occurred in the Central District of California.

THE PARTIES

24 4. Relator is a resident and citizen of the United States, the State of California, and
25 of this District. Relator brings this action of behalf of the Government under 31 U.S.C. §
26 3730(b) and on behalf of the States of California, New York, New Jersey, Florida, Texas,
27 Michigan, Massachusetts, Maryland and Illinois under California Government Code 12652(c),
28 New York State Finance Law § 190(2), New Jersey Statutes Annotated § 2A:32C-5, Florida

1 Statutes § 68.083, Texas Human Resources Code § 36.101(a), Michigan Comp. Laws §§
2 400.610a(1), Massachusetts General Laws Chapter 12, §§ 5C(2), Maryland Code, Health
3 General § 2-604(a)(1), and 740 Illinois Comp. Stat. § 175/4(b)(1), respectively. The
4 Government funds, pays for, partially funds or partially pays for various health insurance
5 programs, including but not limited to the Medicare and Medicaid programs, Champus, and
6 Federal Employees Health Benefits Insurance Plans. Each of the Certain States funds, pays
7 for, partially funds or partially pays for various health insurance programs, including but not
8 limited to the Medicaid program administered in each of such Certain States.

9 5. Defendants Reckitt Benckiser Pharmaceuticals, Inc. and Reckitt Benckiser
10 (USA), Inc. (collectively, "Reckitt"), and MonoSol Rx, LLC (MonoSol) are, and at all times
11 mentioned were, corporations formed under the laws of the State of Delaware, and transacted
12 business in, among other places, the Central District of California.

13 INTRODUCTION

14 6. Buprenorphine, the active agent in Subutex and Suboxone to treat opioid
15 dependence, is a synthetic opioid. In appropriate situations, dosages, frequency and duration
16 of use, buprenorphine can reduce or remove an opioid dependent patient's craving for the
17 abused opioid drug. However, buprenorphine can also result in the patient being addicted to
18 buprenorphine when administered in the dosage amounts and duration recommended by
19 Reckitt.

20 7. Reckitt obtained government approval to market and distribute buprenorphine,
21 formulated as Subutex and Suboxone, to treat patients with opioid dependence (i.e., addiction)
22 based upon studies concerning the treatment of intravenous drug abusers addicted to illicit
23 opioid drugs such as heroin. Reckitt marketed and promoted its products for the maintenance
24 treatment and detoxification of patients with opioid dependency.¹ Reckitt's labeling, such as
25 the Package Insert, of Subutex and Suboxone states that use of these medications are
26 appropriate for treatment of opioid dependence, but fails to differentiate the appropriate usage,

27
28 ¹As used herein, "opioid dependency" includes opioid addiction as well as physical dependence on an opioid.

1 dosage, frequency or duration of usage for treatment of patients dependent on intravenous
2 opioids, such as heroin, as compared to patients dependent on prescription opioids, such as
3 vicodin and oxycodone, in violation of, among other things, 21 U.S.C. § 352(f) and (j), and
4 21 C.F.R. 201.5. While such labeling recommends a usage, dosage, frequency and duration
5 of usage for treatment of patients that may be appropriate for intravenous drug addicts, such
6 recommended usage, dosage, frequency or duration of usage for treatment of patients is
7 excessive for the treatment of prescription opioid dependent patients because such
8 recommended administration can and does result in addiction to the buprenorphine in Subutex
9 and Suboxone. Such misbranding, as well as various misrepresentations and concealments by
10 Reckitt, resulted in a large number of patients with prescription opioid dependency being
11 treated with Subutex and/or Suboxone and becoming addicted to the buprenorphine in Subutex
12 and Suboxone.

13 8. Reckitt marketed and promoted Subutex and Suboxone as being mildly if at all
14 addictive, and that withdrawal symptoms from such medications, if any, were mild as
15 compared to those of full agonist opioids. Reckitt made such misrepresentations as part of its
16 marketing and promotion of Subutex and/or Suboxone for detoxification therapy of opioid
17 dependency, which is an "off-label" use of these medications. In fact, administration of
18 Subutex or Suboxone in the dosage amounts and duration recommended by Reckitt can and
19 does result in addiction to the buprenorphine in such medications with withdrawal syndromes
20 (from being addicted to the buprenorphine in Subutex/Suboxone) as severe as, if not more
21 severe than, the withdrawal symptoms of the opioid drug that triggered the Subutex/Suboxone
22 therapy.

23 9. As discussed below, defendants fraudulently induced treating physicians and
24 their patients to prescribe and utilize Suboxone and/or Subutex for off-label uses and/or
25 medically unnecessary uses or amounts, and caused hospitals, treating physicians, pharmacies
26 and their patients to bill the Government and Certain States for Suboxone and/or Subutex for
27 such improper uses and amounts.

28 ///

COMMON ALLEGATIONS

10. The pharmaceutical industry is highly regulated by the Food and Drug Administration (FDA). Pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§301, *et seq.*, the FDA strictly regulates the content of consumer and physician based advertising, direct to physician product promotion, and drug labeling information used by pharmaceutical companies in promoting and selling FDA approved prescription drugs.

11. Any presentations, promotions or marketing to physicians for products for use other than that approved for labeling purposes by the FDA is considered "off label" marketing and is thus prohibited by FDA regulation. Any failure to fairly and accurately present the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. (*See*, 21 U.S.C. §§331(a) and (b), 352; 21 C.F.R. §§201.5, 201.57.)

12. Pharmaceutical promotion and marketing materials and presentations lacking in fair balance or that are otherwise false and misleading violate the Food, Drug and Cosmetics Act, 21 U.S.C. §§301, *et seq.*, and regulations promulgated thereunder. Such violations exist where promotion and marketing materials and presentations for an FDA approved drug:

- i. Minimize, understate or misrepresent the risks, contra-indications and complications associated with that drug;
- ii. Overstate or misrepresent the risks, contra-indications and complications associated with any competing drugs;
- iii. Reference "off label" uses of the drug for which it was not an approved indication by the FDA, or expressly or impliedly promote unapproved uses and dosing regimens for which the drug is not indicated; or
- iv. Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

13. The Drug Addiction Treatment Act of 2000, Public Law 106-310, Section 3502, (DATA 2000) was passed to establish the regulation of healthcare providers and facilities

1 providing treatment for opioid addiction. With its passage, qualified physicians are able to
2 provide office-based treatment of opioid addiction through the administration of
3 buprenorphine, a Schedule III narcotic, which was formulated as Subutex and Suboxone by
4 Reckitt.

5 14. Prior to DATA 2000's enactment, treatment for heroin addiction could only be
6 performed in stand-alone methadone clinics. After DATA 2000, qualified physicians were
7 initially licensed to administer Subutex and Suboxone to up to 30 patients, which can be
8 increased up to 100 patients per qualified physician after they had one year's experience with
9 administering Subutex and Suboxone.

10 15. Reckitt was granted an orphan drug status for Subutex and Suboxone, resulting
11 in an additional two years of exclusivity to the drug, and is usually only granted when the total
12 number of potential patients is less than 250,000. Reckitt used projected data based solely on
13 potential intravenous opioid drug abusers to support its application and did not present any
14 evidence of the large number of patients with prescription opioid dependency who would
15 potentially receive Subutex and Suboxone therapy. In reality, prescription opioid dependency
16 patients, as opposed to intravenous drug abusers, are the predominate group of patients
17 receiving Subutex/Suboxone therapy.

18 16. During or about 2002, Reckitt began marketing buprenorphine in the United
19 States under the names Subutex and Suboxone as sublingual tablets for the treatment of opioid
20 dependence. The tablets were manufactured in dosage amounts of 2 mg and 8 mg of
21 buprenorphine, with Suboxone containing small doses of Naloxone (.5 mg and 2 mg,
22 respectively) to deter Suboxone's abuse and diversion potential by intravenous drug users
23 when administered outside of an in-patient setting.

24 17. Reckitt's initial national Subutex/Suboxone marketing campaigns used Medical
25 Thought Leaders (MTLs) to train a paid panel of Physician Treatment Advocates (PTAs). The
26 MTLs and PTAs were Reckitt's representatives and/or agents in defendants'
27 Subutex/Suboxone marketing campaign. The PTAs then repeated the MTLs' statements and
28 provided other Reckitt promotional materials to healthcare providers, including treating

1 physicians prescribing and administering Subutex and Suboxone, concerning the
2 characteristics, use, dosage, frequency and duration of treatment of Subutex and Suboxone.
3 PTAs received at least \$500 for each talk they gave, whether in front of a large group of
4 healthcare providers or a one on one meeting with another physician or health care
5 professional.

6 18. The MTLs' lectures to the PTAs stressed, among other things, that (a) Subutex
7 and Suboxone are mildly if at all addictive, (b) Subutex and Suboxone cause less euphoria than
8 full agonist opioids and are thus less addictive, and (c) Subutex and/or Suboxone therapy could
9 be stopped abruptly without problem. In fact, each such representation was false and Reckitt
10 made these misrepresentations (and/or caused them to be made to treating healthcare
11 providers) knowing that they were false and misleading in spite of mounting evidence to the
12 contrary. Patients become addicted to Subutex and Suboxone easily after administration in the
13 dosage amount and duration recommended by Reckitt with withdrawal syndromes as severe,
14 if not more severe, than the withdrawal symptoms from the full agonist opioids. At all times
15 relevant, defendants knew, acted in deliberate ignorance, and/or acted in deliberate disregard
16 of these facts, but intentionally refused and/or failed to advise physicians of same. These
17 statements were continuously made by Reckitt's MTLs in front of large audiences of PTAs
18 and other physicians licensed to prescribe Subutex and Suboxone. In turn, the PTAs repeated
19 these misstatements to treating physicians and other healthcare providers that prescribed or
20 administered Subutex and Suboxone, as well as to patients.

21 19. By misrepresenting that Subutex and Suboxone were mildly if at all addictive,
22 were less addictive than full agonist opioids, and/or that Subutex/Suboxone therapy could be
23 stopped abruptly without problem, Reckitt concealed the risks associated with such therapy.
24 Such misrepresentations and concealments resulted in the improper use, dosage, frequency
25 and/or duration of such therapy because treating physicians were unaware of the addictive
26 qualities of Subutex and Suboxone, particularly when administered in the dosage amount and
27 duration recommended by Reckitt and/or with patients with prescription opioid dependency.
28 Further, such misrepresentations concealed the risks of such therapy resulting in use of

1 Subutex and Suboxone without the patients' informed consent, given the addictive qualities
2 of Subutex and Suboxone. Such misrepresentations and concealments resulted in the improper
3 prescription and administration of Subutex and Suboxone that were not medically necessary.

4 Misbranding

5 20. Reckitt's Package Insert for Subutex and Suboxone states that use of these
6 medications is appropriate for treatment of opioid dependence, but fails to differentiate the
7 appropriate usage, dosage, frequency or duration of usage for treatment of patients with
8 dependence to prescription opioids as compared to intravenous opioid addicts (the latter for
9 whom the dosages and durations were developed) in violation of, among other things, 21
10 U.S.C. § 352(f)(1) and (j), and 21 C.F.R. 201.5. While the Package Insert recommends a
11 usage, dosage, frequency or duration of usage for treatment of patients that may be appropriate
12 for intravenous heroin addicts, such recommended usage, dosage, frequency or duration of
13 usage is excessive for the treatment of prescription opioid dependency patients because such
14 recommended administration will result in prescribing opioids to those patients in greater
15 quantities than the opioids they were originally dependent upon, which results in addiction to
16 the buprenorphine in Suboxone and Subutex that is more profound than the dependence for
17 which treatment was sought. Such misbranding, as well as various misrepresentations and
18 concealments by Reckitt, resulted in a large number of prescription opioid dependency patients
19 being treated with Subutex and/or Suboxone and becoming addicted to the buprenorphine in
20 Subutex and Suboxone.

21 21. As a result of Reckitt's misbranding and false statements, treating physicians
22 inappropriately administered Subutex and Suboxone to treat (a) patients with physical
23 dependency to opioids who were not opioid addicted, resulting in a large number of such
24 patients becoming addicted to the buprenorphine in Subutex and Suboxone, and (b)
25 prescription opioid addicted patients in a dosage, frequency or duration of usage for treatment
26 that was excessive for the treatment of prescription opioid addicted patients because such
27 recommended administration results (and resulted) in a large number of such patients
28 becoming addicted to the buprenorphine in Subutex and Suboxone. Reckitt thus caused

1 physicians, hospitals, pharmacies and patients to present false claims for payment to Medicare,
2 Medicaid, and other government funded health plans.

3 Off Label Use - Detoxification

4 22. Reckitt and its representatives actively and continuously marketed and promoted
5 Suboxone and Subutex to physicians for detoxification treatment since the original release of
6 those medications (Reckitt stopped promoting Subutex for detoxification when Reckitt starting
7 marketing Suboxone film). Reckitt was so effective in marketing Suboxone film for
8 detoxification treatment that it is the sole detoxification treatment that most private health
9 insurance carriers will authorize for detoxification treatment in Los Angeles and Orange
10 Counties.

11 23. Initially, Reckitt instructed treating physicians to administer Subutex and
12 Suboxone for short term detoxification treatment (one or two weeks), and provided MTLs,
13 PTAs and prescribing physicians with detoxification treatment taper schedules. Shortly
14 thereafter, Reckitt's MTLs and pharmaceutical salespersons supplemented the short term
15 detoxification schedules with recommendations for long term detoxification and maintenance
16 treatment protocols for using Subutex and Suboxone to the PTAs (ostensibly to reduce
17 recidivism). In turn, the PTAs repeated these long-term detoxification and maintenance
18 treatment protocols and representations to treating physicians and other healthcare providers
19 that prescribed or administered Subutex and Suboxone.

20 24. At all times relevant, the FDA only approved Suboxone for maintenance
21 treatment and Subutex for induction and maintenance treatment, but did not approve either for
22 detoxification treatment as those terms are defined by the Controlled Substances Act. (See,
23 21 CFR § 1300.01(b).)

24 25. In reliance upon defendants' false and fraudulent statements, treating physicians
25 prescribed and administered Subutex and Suboxone to opioid dependency patients for
26 detoxification treatment which is an "off label" use. Defendants thus caused physicians,
27 pharmacies, hospitals and patients to present false claims for payment to Medicare, Medicaid,
28 and other government funded health plans.

1 Off Label Use - Induction

2 26. At all times relevant, the FDA approved Subutex for induction (introducing the
3 patient to buprenorphine therapy) and maintenance therapy, and Suboxone for maintenance
4 therapy only. Suboxone was not approved for induction.

5 27. During or about 2009, Reckitt's orphan drug status expired and several other
6 pharmaceutical manufacturers began producing and selling Subutex generically. Defendants
7 responded by introducing a new Suboxone film that defendants claimed significantly deters
8 potential abuse and diversion by intravenous drug users. The Suboxone film is in the same
9 doses and amounts of Naloxone as the Suboxone sublingual tablets. Upon release of the
10 Suboxone film, defendants changed their marketing strategy and discontinued manufacturing,
11 selling or promoting Subutex.

12 28. Since losing its orphan drug status, defendants' marketing and promotion has
13 been that Subutex is too easily abused or diverted by opioid drug abusers to be ethically
14 prescribed, should be illegal, and that only Suboxone film should be used for induction and
15 maintenance treatment for opioid dependence. For instance, Dr. Mendelson, a Reckitt MTL
16 member, strongly cautioned physicians that because of its potential for abuse, prescribing
17 Subutex will result in increased scrutiny from the DEA and potential liability. Dr. Mendelson
18 advised physicians and PTAs that because of the Subutex's abuse potential patients should be
19 inducted directly on Suboxone. These statements contradict Reckitt's long standing Package
20 Insert regarding this issue wherein it recommends inducing patients first on Subutex then
21 moving them to Suboxone, as well as the fact that the FDA specifically only approved
22 Suboxone for maintenance therapy, but not induction. These representations concerning the
23 use of Suboxone film for induction were repeated by the PTAs to healthcare providers that
24 prescribed and administered Suboxone film.

25 29. In reliance upon defendants' statements during and after 2009, hospitals and
26 treating physicians prescribed and administered Suboxone film (as opposed to Subutex or its
27 generic equivalent) for induction treatment of patients, which is an "off label" use. Defendants
28 thus caused physicians, pharmacies, hospitals and patients to present false claims for payment

1 to Medicare, Medicaid, and other government funded health plans.

2 Misbranding and Off-Label Use - Hospital In-Patient Treatment

3 30. The Relator is informed and believes and thereupon alleges that Reckitt
4 marketed Suboxone film to hospitals nationwide for in-patient detoxification and maintenance
5 treatments. Reckitt represented to hospitals that they should only use Suboxone film, and not
6 use generic Subutex, for induction or for any other in-patient treatment because Subutex
7 purportedly poses too great a risk of abuse and diversion to safely administer to patients. For
8 instance, in attempting to market Suboxone film to the Lakewood Regional Medical Center
9 (a hospital owned by national hospital chain Tenet Hospitals), Reckitt informed the hospital
10 pharmacist that St. Jude Hospital System (headquartered in neighboring Orange County) was
11 using Suboxone film exclusively because of its purported lower risk for abuse and diversion
12 as compared to Subutex.

13 31. The true facts are that when patients are admitted to hospitals for in-patient
14 opioid dependence detoxification and/or maintenance treatments, there is no risk that such
15 patients will abuse or divert Subutex, and therefore there is no legitimate reason to administer
16 the more costly Suboxone (which contains Naloxone) as compared to generic Subutex. There
17 is no risk that patients can divert generic Subutex administered to them in an in-patient setting
18 because the hospital staff is present when the patients are administered the dose.

19 32. Reckitt's false statements regarding the purported risk of using Subutex for in-
20 patient treatment of opioid dependency resulted, and continue to result, in hospitals
21 administering the more expensive Suboxone film to hospital patients, some of whom were and
22 are beneficiaries under the Medicare and Medicaid programs, and/or other government funded
23 health plans.

24 False and Fraudulent Statements

25 33. In reliance upon defendants' false and fraudulent statements, treating physicians
26 prescribed and administered Subutex and Suboxone to treat their patients, without disclosure
27 to such patients of the addictive effects of such medications in the dosage amount and duration
28 recommended by defendants. Defendants thus caused physicians, hospitals, pharmacies and

1 patients to present false claims for payment to Medicare, Medicaid, and other government
2 funded health plans.

3 34. As a result of defendants' misrepresentations and concealments, hospitals and
4 treating physicians (a) inappropriately administered Subutex and Suboxone to treat
5 prescription opioid dependency patients resulting in a large number of such patients becoming
6 addicted to the buprenorphine in Subutex and Suboxone, (b) administered Suboxone for
7 induction therapy, and/or (c) administered Subutex and/or Suboxone for detoxification. As
8 a result of such misrepresentations and concealments, defendants caused physicians, hospitals,
9 pharmacies and patients to present false claims for payment to Medicare, Medicaid, and other
10 government funded health plans.

11 35. In reliance upon defendants' statements during and after 2009, treating
12 physicians prescribed and administered Suboxone film (as opposed to Subutex or its generic
13 equivalent) for the induction treatment of patients, a use for which it is not approved by the
14 FDA. Defendants thus caused physicians, hospitals, pharmacies and patients to present false
15 claims for payment to Medicare, Medicaid, and other government funded health plans.

16
17 FIRST CLAIM FOR RELIEF

18 (Violations of the False Claims Act, 31 U.S.C. § 3729(a) against all defendants)

19 36. Relator realleges and incorporates by reference the allegations contained in
20 paragraphs 1 through 35 of this complaint.

21 37. By virtue of the conduct, misrepresentations, concealments described above,
22 defendants knowingly presented, or caused to be presented, to the Government false and
23 fraudulent claims for payment or approval of prescriptions for uses of Subutex and Suboxone.

24 38. By virtue of the conduct, misrepresentations, concealments described above,
25 defendants knowingly made, used, or caused to be made or used, false records or statements
26 material to said false or fraudulent claims.

27 39. Defendants conspired among themselves, and with others, to commit the above
28 described acts.

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1 three times the amount of damages sustained by California as a result of the false and
2 fraudulent practices alleged above.

3 50. As a result of defendants' conduct, California Government Code §12651(a)
4 provides that defendants are liable to California for civil penalties of up to \$10,000 for each
5 such false and fraudulent claim, statement or act.

6 51. Relator is also entitled to recover his attorneys fees, costs and expenses from
7 defendants, and each of them, pursuant to California Government Code § 12652(g)(8).

8
9 THIRD CLAIM FOR RELIEF

10 (Violation of New York State Finance Law § 189(1) against all defendants)

11 52. Relator realleges and incorporates by reference the allegations contained in
12 paragraphs 1 through 35 of this complaint.

13 53. By virtue of the conduct, misrepresentations, concealments described above,
14 defendants knowingly presented, or caused to be presented to New York false and fraudulent
15 claims for payment or approval of prescriptions for uses of Subutex and Suboxone.

16 54. By virtue of the conduct, misrepresentations, concealments described above,
17 defendants knowingly made, used, or caused to be made or used, false records or statements
18 material to said false or fraudulent claims.

19 55. Defendants conspired among themselves, and with others, to commit the above
20 described acts.

21 56. New York, unaware of the falsity or fraudulent nature of the claims that
22 defendants caused to be presented, paid for claims that would otherwise not have been
23 allowed.

24 57. As a result of the defendants' conduct, defendants are liable to New York for
25 three times the amount of damages sustained by New York as a result of the false and
26 fraudulent practices alleged above.

27 58. As a result of defendants' conduct, New York State Finance Law § 189(1)(g)
28 provides that defendants are liable to New York for civil penalties of up to \$12,000 for each

1 such false and fraudulent claim, statement or act.

2 59. Relator is also entitled to recover his attorneys fees, costs and expenses from
3 defendants, and each of them, pursuant to New York State Finance Law § 190(7).

4
5 FOURTH CLAIM FOR RELIEF

6 (Violation of New Jersey Statutes Annotated § 2A:32C-3 against all defendants)

7 60. Relator realleges and incorporates by reference the allegations contained in
8 paragraphs 1 through 35 of this complaint.

9 61. By virtue of the conduct, misrepresentations, concealments described above,
10 defendants knowingly presented, or caused to be presented to New Jersey false and fraudulent
11 claims for payment or approval of prescriptions for uses of Subutex and Suboxone.

12 62. By virtue of the conduct, misrepresentations, concealments described above,
13 defendants knowingly made, used, or caused to be made or used, false records or statements
14 material to said false or fraudulent claims.

15 63. Defendants conspired among themselves, and with others, to commit the above
16 described acts.

17 64. New Jersey, unaware of the falsity or fraudulent nature of the claims that
18 defendants caused to be presented, paid for claims that would otherwise not have been
19 allowed.

20 65. As a result of the defendants' conduct, defendants are liable to New Jersey for
21 three times the amount of damages sustained by New Jersey as a result of the false and
22 fraudulent practices alleged above.

23 66. As a result of defendants' conduct, N.J.S.A § 2A:32C-3 provides that defendants
24 are liable to New Jersey for civil penalties of up to \$10,000 for each such false and fraudulent
25 claim, statement or act.

26 67. Relator is also entitled to recover his attorneys fees, costs and expenses from
27 defendants, and each of them, pursuant to N.J.S.A. § 2A:32C-8.

28

FIFTH CLAIM FOR RELIEF

(Violation of Florida Statutes § 68.082(2) against all defendants)

68. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 35 of this complaint.

69. By virtue of the conduct, misrepresentations, concealments described above, defendants knowingly presented, or caused to be presented to Florida false and fraudulent claims for payment or approval of prescriptions for uses of Subutex and Suboxone.

70. By virtue of the conduct, misrepresentations, concealments described above, defendants knowingly made, used, or caused to be made or used, false records or statements material to said false or fraudulent claims.

71. Defendants conspired among themselves, and with others, to commit the above described acts.

72. Florida, unaware of the falsity or fraudulent nature of the claims that defendants caused to be presented, paid for claims that would otherwise not have been allowed.

73. As a result of the defendants' conduct, defendants are liable to Florida for three times the amount of damages sustained by Florida as a result of the false and fraudulent practices alleged above.

74. As a result of defendants' conduct, Florida Statutes § 68.082(2) provides that defendants are liable to Florida for civil penalties of up to \$11,000 for each such false and fraudulent claim, statement or act.

75. Relator is also entitled to recover his attorneys fees, costs and expenses from defendants, and each of them, pursuant to Florida Statutes § 68.086.

SIXTH CLAIM FOR RELIEF

(Violation of Texas Human Resources Code § 36.002 against all defendants)

76. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 35 of this complaint.

77. By virtue of the conduct, misrepresentations, concealments described above,

1 defendants knowingly presented, or caused to be presented to Texas false and fraudulent
2 claims for payment or approval of prescriptions for uses of Subutex and Suboxone.

3 78. By virtue of the conduct, misrepresentations, concealments described above,
4 defendants knowingly made, used, or caused to be made or used, false records or statements
5 material to said false or fraudulent claims.

6 79. Defendants conspired among themselves, and with others, to commit the above
7 described acts.

8 80. Texas, unaware of the falsity or fraudulent nature of the claims that defendants
9 caused to be presented, paid for claims that would otherwise not have been allowed.

10 81. As a result of the defendants' conduct, defendants are liable to Texas for two
11 times the amount of damages sustained by Texas as a result of the false and fraudulent
12 practices alleged above.

13 82. As a result of defendants' conduct, Texas Human Resources Code § 36.052(a)(3)
14 provides that defendants are liable to Texas for civil penalties of up to \$15,000 for each such
15 false and fraudulent claim, statement or act.

16 83. Relator is also entitled to recover his attorneys fees, costs and expenses from
17 defendants, and each of them, pursuant to Texas Human Resources Code § 36.110(c).

18
19 **SEVENTH CLAIM FOR RELIEF**

20 (Violation of Michigan Comp. Laws §§ 400.603 and 400.607 against all defendants)

21 84. Relator realleges and incorporates by reference the allegations contained in
22 paragraphs 1 through 35 of this complaint.

23 85. By virtue of the conduct, misrepresentations, concealments described above,
24 defendants knowingly presented, or caused to be presented to Michigan false and fraudulent
25 claims for payment or approval of prescriptions for uses of Subutex and Suboxone.

26 86. By virtue of the conduct, misrepresentations, concealments described above,
27 defendants knowingly made, used, or caused to be made or used, false records or statements
28 material to said false or fraudulent claims.

1 87. Defendants conspired among themselves, and with others, to commit the above
2 described acts.

3 88. Michigan, unaware of the falsity or fraudulent nature of the claims that
4 defendants caused to be presented, paid for claims that would otherwise not have been
5 allowed.

6 89. As a result of the defendants' conduct, defendants are liable to Michigan for
7 three times the amount of damages sustained by Michigan as a result of the false and
8 fraudulent practices alleged above.

9 90. As a result of defendants' conduct, Michigan Comp. Laws § 400.612(1)
10 provides that defendants are liable to Michigan for civil penalties of up to \$10,000 for each
11 such false and fraudulent claim, statement or act.

12 91. Relator is also entitled to recover his attorneys fees, costs and expenses from
13 defendants, and each of them, pursuant to Michigan Comp. Laws § 400.610a(9).

14
15 EIGHTH CLAIM FOR RELIEF

16 (Violation of Massachusetts General Laws Chapter 12, § 5B against all defendants)

17 92. Relator realleges and incorporates by reference the allegations contained in
18 paragraphs 1 through 35 of this complaint.

19 93. By virtue of the conduct, misrepresentations, concealments described above,
20 defendants knowingly presented, or caused to be presented to Massachusetts false and
21 fraudulent claims for payment or approval of prescriptions for uses of Subutex and Suboxone.

22 94. By virtue of the conduct, misrepresentations, concealments described above,
23 defendants knowingly made, used, or caused to be made or used, false records or statements
24 material to said false or fraudulent claims.

25 95. Defendants conspired among themselves, and with others, to commit the above
26 described acts.

27 96. Massachusetts, unaware of the falsity or fraudulent nature of the claims that
28 defendants caused to be presented, paid for claims that would otherwise not have been

1 allowed.

2 97. As a result of the defendants' conduct, defendants are liable to Massachusetts
3 for three times the amount of damages sustained by Massachusetts as a result of the false and
4 fraudulent practices alleged above.

5 98. As a result of defendants' conduct, Massachusetts General Laws Chapter 12, §
6 5B(9) provides that defendants are liable to Massachusetts for civil penalties of up to \$10,000
7 for each such false and fraudulent claim, statement or act.

8 99. Relator is also entitled to recover his attorneys fees, costs and expenses from
9 defendants, and each of them, pursuant to Massachusetts General Laws Chapter 12, § 5F.

10

11 NINTH CLAIM FOR RELIEF

12 (Violation of Maryland Code, Health General § 2-602(a) against all defendants)

13 100. Relator realleges and incorporates by reference the allegations contained in
14 paragraphs 1 through 35 of this complaint.

15 101. By virtue of the conduct, misrepresentations, concealments described above,
16 defendants knowingly presented, or caused to be presented to Maryland false and fraudulent
17 claims for payment or approval of prescriptions for uses of Subutex and Suboxone.

18 102. By virtue of the conduct, misrepresentations, concealments described above,
19 defendants knowingly made, used, or caused to be made or used, false records or statements
20 material to said false or fraudulent claims.

21 103. Defendants conspired among themselves, and with others, to commit the above
22 described acts.

23 104. Maryland, unaware of the falsity or fraudulent nature of the claims that
24 defendants caused to be presented, paid for claims that would otherwise not have been
25 allowed.

26 105. As a result of the defendants' conduct, defendants are liable to Maryland for
27 three times the amount of damages sustained by Maryland as a result of the false and
28 fraudulent practices alleged above.

106. As a result of defendants' conduct, Maryland Code, Health General § 2-602(b)(1)(I) provides that defendants are liable to Maryland for civil penalties of up to \$10,000 for each such false and fraudulent claim, statement or act.

107. Relator is also entitled to recover his attorneys fees, costs and expenses from defendants, and each of them, pursuant to Maryland Code, Health General § 2-604(a)(2)(ii).

TENTH CLAIM FOR RELIEF

(Violation of 740 Illinois Comp. Stat. § 175/3 against all defendants)

108. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 35 of this complaint.

109. By virtue of the conduct, misrepresentations, concealments described above, defendants knowingly presented, or caused to be presented to Illinois false and fraudulent claims for payment or approval of prescriptions for uses of Subutex and Suboxone.

110. By virtue of the conduct, misrepresentations, concealments described above, defendants knowingly made, used, or caused to be made or used, false records or statements material to said false or fraudulent claims.

111. Defendants conspired among themselves, and with others, to commit the above described acts.

112. Illinois, unaware of the falsity or fraudulent nature of the claims that defendants caused to be presented, paid for claims that would otherwise not have been allowed.

113. As a result of the defendants' conduct, defendants are liable to Illinois for three times the amount of damages sustained by Illinois as a result of the false and fraudulent practices alleged above.

114. As a result of defendants' conduct, 740 Illinois Comp. Stat. § 175/3(a)(1)(G) provides that defendants are liable to Illinois for civil penalties of up to \$11,000 for each such false and fraudulent claim, statement or act.

115. Relator is also entitled to recover his attorneys fees, costs and expenses from defendants, and each of them, pursuant to 740 Illinois Comp. Stat. § 175/4(d).

1 PRAYER FOR RELIEF


2 WHEREFORE, Relator prays for relief against the defendants, and each of them, as
3 follows:

- 4 1. Treble the damages of the Government and the Certain States according to
5 proof;
6 2. Civil penalties according to proof;
7 3. A relator's award measured as a percentage of the amounts recovered by or on
8 behalf of the Government and the Certain States in an amount according to proof;
9 4. Attorney's fees, expenses, and costs; and
10 5. Such other and further relief as the Court deems just and proper.

11
12 THE ZINBERG LAW FIRM
13 A Professional Corporation

14 THE HANAGAMI LAW FIRM
15 A Professional Corporation

16 Dated: July 8, 2013

17 By: 
18 William K. Hanagami
19 Attorneys for Plaintiff and Qui Tam Relator

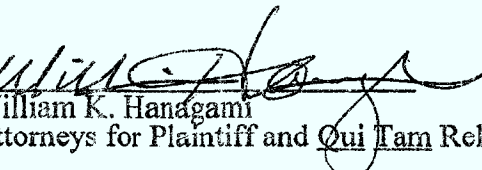
20 REQUEST FOR JURY TRIAL

21 Plaintiff and Qui Tam Relator hereby requests a trial by jury.

22 THE ZINBERG LAW FIRM
23 A Professional Corporation

24 THE HANAGAMI LAW FIRM
25 A Professional Corporation

26 Dated: July 8, 2013

27 By: 
28 William K. Hanagami
Attorneys for Plaintiff and Qui Tam Relator

Complaint.P03.wpd

PROOF OF SERVICE

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES)

I, the undersigned, certify and declare that I am over the age of 18 years, employed in the County of Los Angeles, State of California, and not a party to the above-entitled cause.

On January 8, 2014, I served a true copy of:

SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT, CALIFORNIA FALSE CLAIMS ACT, NEW YORK FALSE CLAIMS ACT, NEW JERSEY FALSE CLAIMS ACT, FLORIDA FALSE CLAIMS ACT, TEXAS FALSE CLAIMS ACT, MICHIGAN FALSE CLAIMS ACT, MASSACHUSETTS FALSE CLAIMS ACT, MARYLAND FALSE CLAIMS ACT, ILLINOIS FALSE CLAIMS ACT; REQUEST FOR JURY TRIAL.

by depositing it in the United States Mail at Woodland Hills, California in a sealed envelope with the postage thereon fully prepaid addressed to the following:

Shana T. Mintz
OFFICE OF
THE UNITED STATES ATTORNEY
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Attorneys for State of California

Abram J. Zinberg
THE ZINBERG LAW FIRM, A.P.C.
412 Olive Avenue, Suite 528
Huntington Beach, CA 92648

Co-Counsel for Relator

Executed on January 8, 2014 at Woodland Hills, California.

I hereby certify that I am a member of the Bar of the United States District Court, Central District of California.

I hereby certify under the penalty of perjury that the foregoing is true and correct.


William K. Hanagami